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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,440	03/30/2001	Lucio Miele	4239-58051	1318

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EXAMINER

EPPS, JANET L.

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,440

Applicant(s)

MIELE ET AL.

Examiner

Janet L Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-10, 17-18, and 22-25, 27-32, 34-35, 72-76, and 78-79, drawn to a method of inducing apoptosis in a target cell comprising administering an antibody that antagonizes the function of Notch protein.

Group II, claim(s) 1-16, 26, 33, 72-77, and 79, drawn to a method of inducing apoptosis in a target cell comprising administering an oligonucleotide that antagonizes the expression of Notch protein.

Group III, claim(s) 19-21, and claims 57-59, 62-71, drawn to an antibody generated against the human Notch-1 EGF-repeats 11 and 12, a hybridoma thereof, pharmaceutical compositions thereof, and a method of generating an antibody.

Group IV, claim(s) 36-45, drawn to a method of stimulating differentiation in a target cell comprising administering a differentiation agent and an antibody against human Notch-1 EGF-repeats 11 and 12.

Group V, claim(s) 46-49, drawn to a method of treating a tumor in a subject, wherein the tumor is characterized by an over expression of Notch protein, wherein said method comprising administering an oligonucleotide that interferes with Notch protein expression.

Group VI, claim(s) 46-47, and 49-51, drawn to a method of treating a tumor in a subject, wherein the tumor is characterized by an overexpression of Notch protein, comprising administering an antibody to a Notch protein.

Group VII, claim(s) 52-56, drawn to a method of diagnosing and staging tumor cells which over express Notch relative to Notch levels in a same tissue type that is non-neoplastic, comprising using an antibody generated against Notch.

Group VIII, claim(s) 59-61, drawn to a pharmaceutical composition comprising a differentiation inducing agent and a molecule that specifically interferes with expression of, or cell fate determining function of, Notch protein, wherein the agent is an oligonucleotide comprising at least six nucleotides from a sequence complementary to an RNA transcript of a Notch gene.

Art Unit: 1635

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The subject matter of the present invention relates to therapeutic compositions comprising antisense nucleic acids or anti-Notch neutralizing antibodies which antagonize Notch function, and their use to treat and detect cancers by inhibiting Notch function or expression. However, the subject matter of the present invention does not correspond to a technical feature that makes a contribution over the prior art. For example, WO 94/07474 discloses antibodies directed against the EGF-repeats 11 and 12 of human Notch protein (see page 14, line 7), and Notch antisense oligonucleotides that comprise a sequence that is antisense to the sequence encoding EGF-repeats 11 and 12 of human Notch-1 (see page 32, lines 23-27). These compositions are disclosed as being useful for the therapeutic treatment of malignancies (e.g. cervical cancers) by inhibiting Notch function (pages 18-22).

Therefore, Groups I-VIII do not relate to a single general inventive concept.

3. Furthermore, groups I-VIII recite multiple processes of use, however 37 CFR 1.475(b) does not provide for multiple independent products or processes. Therefore, the instant invention groups are deemed to lack unity of invention.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

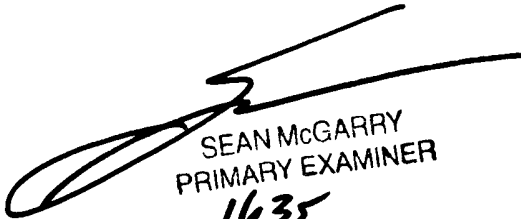
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
March 3, 2003


SEAN McGARRY
PRIMARY EXAMINER
1635